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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,775	01/08/2002	Richard A. Gatti	UC081.001A	5310

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EXAMINER	
MARVICH, MARIA	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 03/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/042,775	GATTI ET AL.	
	Examiner	Art Unit	
	Maria B. Marvich, PhD	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5,10-13,15-19,21 and 32-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *2, 5, 10-13, 15 and 16* is/are allowed.

6)☒ Claim(s) *17-19,21 and 32-36* is/are rejected.

7)☒ Claim(s) *1 and 16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to an amendment and Declaration filed 12/17/04. Claims 3, 4, 6-9, 14, 20 and 22-31 have been canceled. Claims 32-36 are new. Claims 1, 2, 5, 10-13, 15-19, 21 and 32-36 are pending.

Response to Amendment

Any rejection of record in the previous action not addressed in this office action is withdrawn. There are no new grounds of rejection herein and therefore, this action is final.

Claim Objections

Claims 1 and 16 are objected to because of the following informalities: In claim 1, L3 is abbreviated and in claim 16, PHAS-1 is abbreviated. For clarity, the first occurrence of an abbreviate word should be spelled out.. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-19, 21 and 23-31 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed

invention. **This rejection is maintained for reasons of record in the office action mailed 8/24/04 and restated below.**

Applicants recite a method of producing recombinant ATM in mammalian cells in which functional ATM protein is produced at levels greater than 5 μg (10 μg, 20 μg, 30 μg) per 8x 10^6 host cells. Applicants recite a broad genus of host cells for ATM production.

The written description requirement for genus claims may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with known or disclosed correlations between function and structure, or by a combination of such characteristics sufficient to show that the applicant was in possession of the claimed genus.

The instant invention is drawn to a method of producing recombinant ATM in mammalian cells. In the instant case, the specification discloses two cell lines, L3 ATM deficient cells and HeLa cells ATM expressing cells, for the production of ATM. Upon infection of HeLa cells with a vaccinia viral vector expressing ATM, it is stated that 0.3-0.5 μg /μl of ATM is purified and more preferably 2 μg per 300 grams of tissue and at levels greater than 5 μg (10 μg, 20 μg, 30 μg) per 8x 10^6 host cells. L3 (ATM deficient) cells are infected with vaccinia viral vector expressing ATM but the levels of ATM are not indicated. Instead, L3 cells are used for the detection of ATM in Western blot analysis and in *in vitro* kinase assays (page 9, line 8-page 10, line 2). The disclosure only teaches that yields of greater than 2 μg per 300 grams of tissue are attained when vaccinia viral vector is used in HeLa cells. The prior art with the exception of Chan et al, which teaches purification of 2 μg of endogenous ATM from 300 grams

of non-transfected placenta tissue (see page 3, line 9-13 of the instant specification) does not teach yield per cell number or weight from mammalian cells. By disclosing yields of ATM from HeLa cells, the applicants have not reduced to practice the claimed invention and the relationship between structure of the host cell and protein production is unclear. In an unpredictable art, the disclosure of one example in one genus would not represent to the skilled artisan a representative number of species sufficient to show applicants were in possession of claimed genus.

Response to Argument

Applicants traverse the claim rejections under 35 U.S.C. 112, first paragraph on pages 5-7 of the amendment filed 12/27/05. First, applicants argue that the specification has contemplated a variety of host cells as demonstrated by the specification, which teaches that mammalian and preferably human cells are to be infected with recombinant virus comprising ATM coding sequences. As well, applicants argue that the specification teaches yields based on mass of tissue or quantity of cells. Therefore, applicants argue that they were in possession of the instant invention. Secondly, applicants' base their arguments upon the Declaration of Helen Chun. The arguments are the following. 1) Vaccinia virus can be used to infect several different types of mammalian cells such as HeLa, L3 and CV-1 cells. 2) Protein expression from transfected CV-1 cells were visually examined and in Dr. Chun's opinion showed comparable levels with related Western blots demonstrating the expression of ATM from HeLa and L3 cells.

Applicants' arguments filed 12/27/05 have been fully considered but they are not persuasive. Applicants have argued that the instantly claimed process generates ATM protein in quantities that were previously unattainable and hence the instant invention is an improvement

over the prior art (see Response filed 6/3/04 page 6, last sentence). Specifically, in claims 17-19, 21 and 32-36, applicants recite that this yield is 2 μg to 5 μg per 300 grams of fresh weight of mammalian cells. The specification discloses that 2 μg to 5 μg per 300 grams of fresh weight can be obtained from HeLa cells infected with recombinant vaccinia virus. It is noted that HeLa cells express ATM endogenously. Levels of ATM are not disclosed but it is noted that the specification teaches use of L3 for the detection of ATM in Western blot analysis and in *in vitro* kinase assays presumably because it is ATM deficient and detection of ATM in these cells would not be contaminated with endogenous ATM. In the Declaration, expression of ATM from CV-1 cells infected with vaccinia expressing ATM is demonstrated. The Declaration relies on visual examination of 3 Western blots as evidence that cells infected with recombinant vaccinia virus express ATM to the recited levels. This data is insufficient. Each of the blots indicates that ATM is detected in the cells. However, the band correlative to ATM does not of itself provide any quantitative data without knowing how many cells were used to generate the sample.. Furthermore, the amount of protein that is represented by the band would need to be known. There are no controls on the gel that indicate that that would even be able to be computed. The levels between gels cannot even be compared without proper controls. Thus there is no way to know whether any of the blots represents 2 μg to 5 μg per 300 grams of fresh weight regardless of whether that be tissue or cell. The disclosure of a single member of this genus does not suggest that the applicant was in possession of the genus of mammalian cells.

Conclusion

Claims 2, 5, 10-13 and 15-16 are allowed.

Claims 1 and 6 are objected to for minor informalities.

Claims 17-19, 21 and 32-36 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (571)-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD
Examiner
Art Unit 1636

March 11, 2005

GERRY LEFFERS
PRIMARY EXAMINER